



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

159
8-2001

02 21 2001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Science Review in Support of the Registration of the TGA/MP Product Bedoukain Z-11-Hexadecenal Technical Pheromone (EPA File Symbol No. 052991-RU), containing 93.0% Z-11-Hexadecenal (Chemical No. 120001) as its Active Ingredient. Review of Product Chemistry Studies. DP Barcode D273381; Case No. 068834; Submission No. S593303; MRID No. 453284-01.

FROM: Russell S. Jones, Ph.D., Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

THRU: Freshteh Toghrol, Ph.D., Senior Scientist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

TO: Andrew Bryceland, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

ACTION REQUESTED

In response to a request for additional information (see Memorandum from R. S. Jones to A. Bryceland, dated 12/06/2000), Bedoukian Research, Inc. submitted additional product chemistry data/information for the TGA/MP product, Bedoukain Z-11-Hexadecenal Technical Pheromone (EPA File Symbol. No. 52991-RU) containing 93% Z-11-hexadecenal as its active ingredient. In support of the registration, the registrant has submitted data/information pertaining to the manufacturing process, certified limits, and analytical methods (MRID No.453285-01), as well as a revised Confidential Statements of Formula (CSF; dated 02/08/2001) for the basic formulation, and a revised label.

CONCLUSIONS AND RECOMMENDATIONS

1. The submitted supplementary product chemistry data are acceptable to support the registration of Bedoukian Z-11-Hexadecenal Technical Pheromone (EPA File Symbol. No. 52991-RU) pending resolution of the CSF deficiencies described in Conclusions 2 and 3.
2. Since the registrant has one formulation that contains an intentionally added [REDACTED] and a second formulation that (on customer demand) does not contain the [REDACTED] the registrant actually has a basic and an alternate formulation of the TGA/MP. The registrant must submit an alternate formulation CSF for the formulation that does not contain the [REDACTED]
3. The CSF for the basic formulation is unacceptable, but upgradable. To upgrade the CSF to acceptable, the registrant must submit lower certified limits for an intentionally added [REDACTED] with a value that is [REDACTED]. An intentionally added ingredient *cannot* have a lower certified limit <0.00 .

STUDY SUMMARY

Product Chemistry

The registrant submitted product chemistry data/information on the manufacturing process, certified limits, and analytical methods, as well as a revised CSF (dated 02/08/2001), and a proposed label for Bedoukian Z-11-Hexadecenal Technical Pheromone (EPA File Symbol. No. 52991-RU). The registrant states that the [REDACTED] may be added to the final product at a nominal concentration of [REDACTED] by weight. It was further stated that some customers may request their product to be free of the [REDACTED]. Therefore, the registrant actually has a basic formulation (with the [REDACTED]) and an alternate formulation (without the [REDACTED]) rather than a single basic formulation wherein the [REDACTED] may or may not be present. The registrant also re-submitted the original certified limits for the basic formulation that lists the lower certified limit for the [REDACTED]. This certified limit is not correct; an intentionally added ingredient must have a lower certified limit >0.00 . The registrant submitted an acceptable explanation for not submitting a analytical method limit of detection.

CLASSIFICATION: Acceptable pending resolution of the deficiencies detailed in Conclusions 2 and 3 above.

cc: F. Toghrul, R. S. Jones, A. Bryceland, BPPD Subject File
R. S. Jones: F.T. CM2, (703) 308-5071: 03/21/2001

THE FOLLOWING PAGES CONTAIN CONFIDENTIAL BUSINESS INFORMATION

DATA EVALUATION REPORT

Reviewed by: Russell S. Jones, Ph.D. BPPD

Secondary Reviewer: Freshteh Toghrol, Ph.D. BPPD

STUDY TYPE: Product Chemistry (Subdivision M Guidelines 151-10 to 151-17)

DP BARCODE: D273381

CASE No. 068834

SUBMISSION No.: S593303

PC CODE: 120001

TOX. CHEM. No.: None

MRID Nos: 453284-01

TEST MATERIAL: Bedoukian Z-11-Hexadecenal Technical Pheromone (containing 93% active ingredient)

STUDY Nos: None

SPONSOR: Bedoukian Research, Inc., 21 Finance Drive, Danbury, CT 06810-4192

TESTING FACILITY: Bedoukian Research, Inc., 21 Finance Drive, Danbury, CT 06810-4192

TITLES OF REPORTS: Product Chemistry of Bedoukian Z-11-Hexadecenyl Acetate Technical Pheromone

AUTHOR: Robert E. Mahoney

REPORTS ISSUED: February 7, 2001

QUALITY ASSURANCE: The product chemistry studies were not conducted under Good Laboratory Practice (GLP) standards, but standards at the performing laboratory followed the intent of the GLPs. Non-compliance statements in were signed by sponsor/submitter (A. P. Roberts) on 02/07/2001.

Inert ingredient information may be entitled to confidential treatment

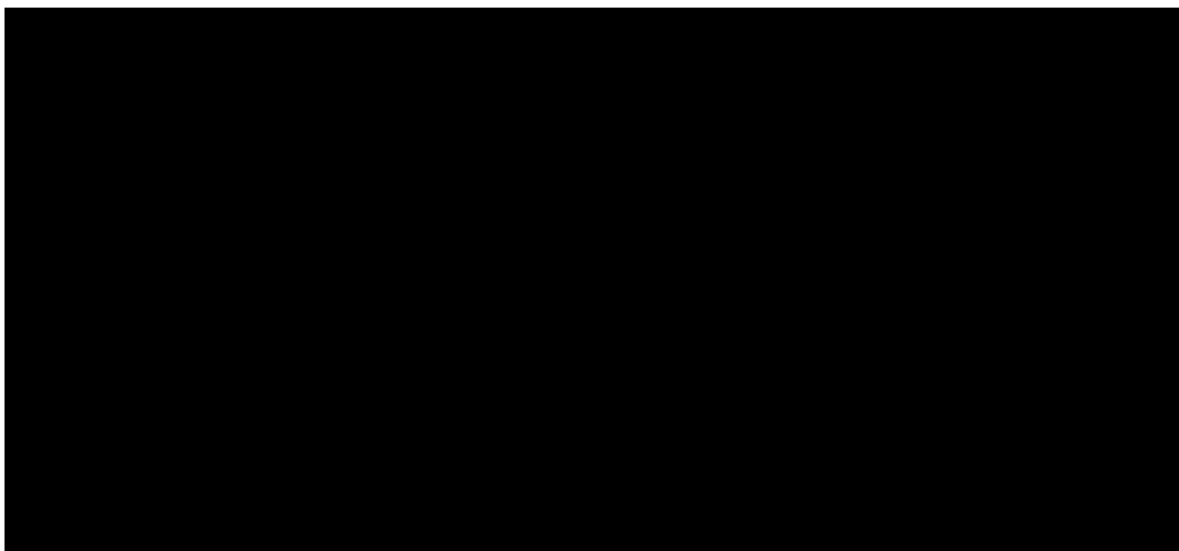
Manufacturing process information may be entitled to confidential treatment

5

SUMMARY: The registrant submitted product chemistry data/information on the manufacturing process, certified limits, and analytical methods, as well as a revised CSF (dated 02/08/2001), and a proposed label. The registrant states that the [REDACTED] may be added to the final product at a nominal concentration of [REDACTED] by weight. It was further stated that some customers may request their product to be free of the [REDACTED]. Therefore, the registrant actually has a basic formulation (with the [REDACTED]) and an alternate formulation (without [REDACTED]), rather than a single basic formulation wherein the [REDACTED] may or may not be present. The registrant also re-submitted the original certified limits for the basic formulation that lists the lower certified limit for the [REDACTED]. This certified limit is not correct; an intentionally added ingredient must have a lower certified limit >0.00. The registrant submitted an acceptable explanation for not determining the analytical method limit of detection for this pheromone product.

CLASSIFICATION: Acceptable pending submission of: (i) a CSF for an alternate formulation that does not contain the [REDACTED] and (ii) a CSF for the basic formulation wherein the lower certified limit for the [REDACTED]

I. MANUFACTURING PROCESS (151-11)



II. CERTIFICATION OF INGREDIENTS (151-15)

In the original submission (MRID 451223-01), the registrant stated that the certified limits for the active and inert ingredients were determined by [REDACTED]

[REDACTED] The nominal concentrations and certified ingredient limits (by % weight) were as follows:

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

6

Ingredient*	% by weight*	Certified Limits (% by weight)*	
		Upper	Lower
Z-11-Hexadecenal	93.00	99.90	90.00

*from CSF dated 02/08/2001

In a reiteration of the discussion presented above in the Manufacturing Process section:

VI. ANALYTICAL METHODS (151-16; OPPTS 830.1800)

The registrant did not submit a limit of detection (LOD) for its analytical method. An LOD was requested in the previous review of the data (see Memorandum from R. S. Jones to A. Bryceland, dated 12/06/2000). An LOD for the analytical method(s) is(are) routinely requested by BPPD of all registrants of TGA/MP products. The registrant provided a detailed explanation of why (in their opinion) an LOD determination would not be practical for their pheromone TGA/MP. This explanation (see attachment) is acceptable. No additional data are required.

Telephone 202 223-4394

Fax 202 872-0745

- c. **Analytical Method.** EPA stated that the analytical method is acceptable pending submission of an acceptable limit of detection. The enclosed addendum to MRID No. 451223-01 states that no limit of detection is provided for the analytical method. The reason for not providing a limit of detection is as follows:

SAN FRANCISCO

100 Stewart Street Tower

One Market

San Francisco, CA 94103

Telephone 415 267-4110

Fax 415 267-4121

- It is the experience of Bedoukian Research, Inc. that determining limits of detection for the analytical method, for pheromone active ingredients, is not practical or necessary. At present, Bedoukian Research, Inc. is registrant of thirteen technical grade pheromone active ingredients, and to date, Bedoukian has not provided limits of detection for the analytical methods of any of those registered pheromones.

SACRAMENTO

712 Fifth Street

Suite 4

Davis, CA 95618

Telephone 530 757-1233

Fax 530 757-1233

- A method of limit detection would be necessary and applicable for a product that is a high dilution of a substance in a solvent. For example, if an end-use formulation of Bedoukian (Z)-11-Hexadecenal Technical Pheromone consisted of an emulsion of the technical pheromone in a sprayable formulation, a method of limit detection would be appropriate in order to verify the actual active ingredient level in the final product. Bedoukian (Z)-11-Hexadecenal is not such a product. It is a manufacturing-use product that contains a minimum of 90% active ingredient.

- The chromatograms provided in the product chemistry volume (MRID No. 451223-01) illustrate the peak height and areas of the active ingredient. Other than the solvent used for sample preparation, which is not integrated in the chromatogram's reports, the active ingredient is the most predominant peak. In our opinion, it is not practical to provide a method of limits of detection for a neat material such as this pheromone. If the active ingredient content of the product is within the certified limits, it is more than 90%, and this will chromatographically resemble the already *subm. Hed det.*

E-mail: tsq@tsqusa.com

<http://www.tsqusa.com>

Confidential Statement of Formula may be entitled to confidential treatment